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Section 5 - 510(k) Summary

1. **Applicant Contact:**

Trudy D. Estridge, PhD
Director of Regulatory Affairs
Angiotech
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Herndon, VA 20171 USA
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JUN 21 2007

Date Prepared: March 01, 2007

2. **Name of Device:** Skater® Biliary Drainage Catheter
Common Name: Biliary Catheter
Classification Name: Catheter, Biliary, Diagnostic
Regulation 21 CFR 876.5010 -- Product Code FGE

3. **Identification of device(s) to which the submitted claims equivalence:**

Boston Scientific Corporation, Flexima™ Biliary Catheter, K023870

4. **Device Description:**

The Skater® Biliary Drainage Catheter is made from hydrophilic coated polyurethane. The catheter comes in a pigtail-loop, locking-type end configuration with drainage holes. The catheters are provided in 8 French, 10 French, and 12 French sizes with a length of 40 cm. Accessories include a metal stiffening cannula, a plastic stiffening cannula and a standard luer locking hub.

5. **Intended Use of the Device:**

The Skater® Biliary Drainage Catheter is indicated for percutaneous biliary drainage.

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6. Technological characteristics of the device in comparison to those of the predicate device(s)

Feature / Technological Characteristics	Boston Scientific Corporation, Flexima™ Biliary Catheter K023870 (Predicate Device)	Skater® Biliary Drainage Catheter (New Device)
Intended Use	Designed for the external and internal percutaneous drainage of the biliary system	Intended for percutaneous biliary drainage
Characteristics	Drainage catheter with metal stiffening cannula, flexible stiffening cannula and luer cap	Drainage catheter with metal and plastic stiffening cannula and female/male luer hub (adapter)
Sizes (French)	8, 10, 12, 14	8, 10, 12
Length (cm)	35 cm from hub to proximal side of pigtail in curved position	40 cm from hub to distal tip in curved position
Lumens	One	One
Distal end configuration	12 side holes and one end hole, pigtail.	8 Fr. – 12 side drainage holes and one end drainage hole, pigtail. 10 and 12 Fr. – 11 side drainage holes and one end drainage hole, pigtail.
Intended anatomical location of distal end	Biliary system	Biliary system
Proximal end configuration	Standard luer locking hub and stop-cock	Female/male luer hub (adapter) and clip
Materials	Polyurethane	Polyurethane
Coating	Hydrophilic	Hydrophilic

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7. Safety and Performance:

The Skater® Biliary Drainage Catheter has been tested and compared to the predicate device. Testing included functional, leakage, catheter body tensile strength and elongation, physical dimensions and catheter body to hub tensile strength. All data gathered demonstrates the Skater® Biliary Drainage Catheter comparably to the predicate device.

The results of *in vitro* bench tests and biocompatibility testing demonstrate the safety and effectiveness of the Skater® Biliary Drainage Catheter.

8. Conclusion

Based on the design, material, function and intended use discussed herein, Angiotech believes the Skater® Biliary Drainage Catheter is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Trudy D. Estridge, Ph.D.
Director of Regulatory Affairs
Angiotech®
Dulles Gateway Center
13921 Park Center Road, Suite 100
HERNDON VA 20171

JUN 21 2007

Re: K070610
Trade/Device Name: Skater® Biliary Drainage Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: June 7, 2007
Received: June 8, 2007

Dear Dr. Estridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510k number if known: K070610

Device Name: Skater® Biliary Drainage Catheter

Indications for Use:

The Skater® Biliary Drainage Catheter is indicated for percutaneous biliary drainage.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070610